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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,639	02/28/2002	Donald J. McMichael	KCX-518B (17507B)	5371
7590	04/13/2004		EXAMINER	
STEPHEN E. BONDURA, ESQ. DORITY & MANNING, P.A. P.O. BOX 1449 GREENVILLE, SC 29602-1449			FOSTER, JIMMY G	
			ART UNIT	PAPER NUMBER
				3728

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,639	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Jimmy G Foster	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 8-10 is/are allowed.
- 6) Claim(s) 1,3-7 and 11-19 is/are rejected.
- 7) Claim(s) 20 and 21 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>15 March 2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

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- 1) The terminal disclaimer with respect to Ser. No 10/085,630 is acknowledged. It is further noted that in Ser. No. 10/085,417 a terminal disclaimer has bee filed which refers to this application. Accordingly, all obviousness-type double patenting rejections have been obviated.
- 2) Claims 8-10 are allowable.
- 3) Claims 1 and 3-7 are finally rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recesses claimed in the first, second and third planar surfaces (in the added limitation in claim 1) are an indefinite double recitation of the plural recesses in lines 3-5 of claim 1, making it unclear what relationship is provided between the two recitations of recesses and making it unclear how many recesses are being required by the claim.

In addition, it is unclear what relationship there is intended to be set forth between the vertical offset recited in line 13 of claim 1 and the offsets set forth in lines 9 and 11 of claim 1.

- 4) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5) Claims 1 and 5 are finally rejected under 35 U.S.C. § 102(b) as being anticipated by Paikoff et al (4,523,679). In the reference of Paikoff et al, there is provided a tray 14. The tray includes a first planar surface defining the uppermost planar surface and the lip of the tray. This planar surface includes a first recess defined by the entire interior periphery of the tray. The folded patient covering means 22 is a first surgical article, and it is located in the recess of said first planar surface.

There is a second planar surface having recesses therein for holding the syringes 18. This second planar surface is below the first planar surface described above.

Additionally, there is provided a third planar surface at a level between the other planar surfaces described above, which has recesses therein that receive the needle caps 18'.

The article located in the recess of the first planar surface described above is placed over at least one of the syringes in the recesses located in the second planar surface described above, such that access to the syringe will be denied until the above article is removed from its position.

In addition, there is a wrapper cover 10 or 28 provided over the tray (see Fig. 1A,4).

6) Claims 11-19 are finally rejected under 35 U.S.C. § 102(b) as being anticipated by Ross et al (5,318,543). It is noted that claims 11-19 of Applicant do not claim the content/articles as structure but as intended use. The kit tray 13 of Ross includes planar surfaces at three different levels:
(1) the surface defined by the peripheral lip of the tray, which includes a

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recess defined by the entire interior of the tray; (2) the surface which includes the recess for holding article 15; and (3) the surface including the recess for holding the syringe 17. Additionally, the reference discloses a container at pouch 20.

Although the reference of Ross shows the container 20 as being placed on the lower planar surface (surface (3) indicated above) over all of the recesses in the lower surface, Applicant does not positively claim the position of the claimed container in the tray as structure but as intended use. Inasmuch as the container 20 of Ross is inherently capable of being disposed on top of the middle level surface (surface (2) indicated above) without extending over the recess which holds article 15, this intended use claimed by Applicant regarding where the container is adapted to rest is met by such capability of the container 20 of Ross.

The recesses of the tray of Ross are inherently capable of holding the articles claimed by Applicant as intended use (and not structure) in claims 11-19.

7) Claims 1 and 5-7 are finally rejected under 35 U.S.C. § 102(b) as being anticipated by Kalinski (5,311,990). It is noted that the limitation, "articles" in line 14 does not particularly refer to surgical articles. Therefore, the limitation positively reciting the articles in the tray, which begins on line 16, does not necessarily require the articles claimed as structure to be surgical articles since they could be the articles referred to in line 14.

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The examiner is now referring to Figure 1 of the Kalinski reference. In the reference of Kalinski there is provided a first planar surface at shoulder 95, circumscribing a recess in which an article/container 55 is received. There appears to be a second planar surface defined by the tops of the pedestals that hold the gun-shaped article between them. The gun-shaped article rests in a recess of that surface, between said pedestals. In addition, there is a planar surface at floor 85 which includes a recess for holding a cord/article near the center of the tray.

The container/article 55 is located over the other articles of the tray such that the other articles cannot be accessed until the container/article is removed from the tray. The reference discloses that the package is intended to be adapted to contain instruments/articles for a surgical procedure.

Said gun-shaped article may be considered to include a handle (a portion of which appears to constitute a trigger on the device), which is shown in Figure 1 to have a V-shaped opening. The planar surface which constitutes the bottom floor 85 is shown in Figure 1 to include an upwardly extending boss which extends into the V-shaped opening of the handle of the gun-shaped article, insofar as Applicant has claimed in claims 6 and 7.

Although it is not clear what is the intended use of the gun-shaped article of claim 1, the examiner asserts that the article is inherently capable of snaring a substance since the article is shown in the figure as having an end which has a scoop or loop (it is hard to tell from the drawing).

A cover is provided at 25.

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8) Claims 3 and 4 would be allowable if appropriately rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

9) Claims 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if appropriately rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10) Applicant's arguments filed Dec. 17, 2003 have been fully considered but they are not deemed to be persuasive. How Kalinski and Ross still read on what Applicant has claimed in claims 1, 5-7 and 11-19 is explained in respective rejections above. Regarding Kalinski, Applicant's claims are not specific enough to keep the container 55 of Kalinski from being considered to define an article corresponding to one of Applicant's claimed articles. Applicant's argument that shoulder 95 is not a planar surface does agree with Figure 2 of the reference. Regarding Ross, Applicant's limitation with respect to the location of the container is one of intended use and not structure.

11) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE

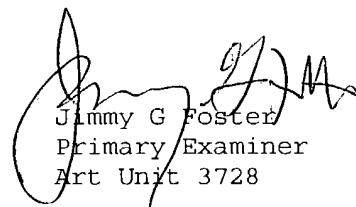
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ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (703) 308-1505. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



Jimmy G Foster
Primary Examiner
Art Unit 3728

JGF
12 April 2004